MAY 1 0 2000

K000521

Summary of Safety and Effectiveness

Encore Orthopedics®, Inc.
9800 Metric Blvd
Austin, TX 78758
512-832-9500

Trade Name: Keystone Hip

Common Name: Cementless hip stem

Classification Name: Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis

Description: The Keystone Hip is available in a variety of proximal bodies and distal stem diameters and length configurations. When viewed in the mediolateral plane the Keystone Hip tapers slightly proximal to distal. The proximal body is trapezoidal in cross-sectional geometry and tapers lateral to medial. The distal stems are cylindrical and the larger sizes have anterior/posterior flutes to decrease the distal stem stiffness.

The Keystone Hip is fabricated from wrought Titanium that conforms to ASTM F136. The outside surface of the proximal body is porous coated with C.P. Titanium beads (ASTM F67) to provide a porous surface. The stem portion is plasma sprayed with CP Titanium. This stem is intended to be press-fit.

This device is modular with the distal stems attached to the bodies via a morse type taper and locking screw.

Intended Use: The Keystone Hip is intended for treatment of patients who are candidates for total hip arthroplasty because the natural femoral head and neck have been affected by osteoarthritis, inflammatory arthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis or femoral neck fracture, and revision arthroplasty.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include same materials, design and indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 0 2000

Ms. Debbie De Los Santos
Regulatory/Clinical Specialist
Encore Orthopedics
9800 Metric Boulevard
Austin, Texas 78758

Re: K000521
Trade Name: Keystone Hip
Regulatory Class: II
Product Codes: LPH
Dated: February 15, 2000
Received: February 16, 2000

Dear Ms. De Los Santos:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000521

Device Name: Keystone Hip

Indications For Use:

Keystone Hip
Indications For Use

The indications for use of the total hip replacement prosthesis include: noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedures where other treatments or devices have failed; and treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, which is unmanageable using other techniques. This stem is to be press-fit.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner

(Division Sign-Off)
Division of General Restorative Devices
(510(k) Number K000521

Prescription Use ✓
(per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)_